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10/802,342	03/17/2004	Peter M.J. Bedding	7593-CIP	3643

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REINHART BOERNER VAN DEUREN S.C.
ATTN: LINDA KASULKE, DOCKET COORDINATOR
1000 NORTH WATER STREET
SUITE 2100
MILWAUKEE, WI 53202

EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/802,342	BEDDING ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) *39-60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/24/04; 11/09/06; 01/25/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicant's election, filed 11/13/2007, IDS filed 01/25/2007, IDS filed 11/09/2006, and IDS filed 05/24/2004.

Claims 1-60 are pending.

Election/Restrictions

1. Applicant's election with traverse of Invention I, claims 1-38 in the reply filed on 11/13/2007 is acknowledged. The traversal is on the ground(s) that the inventions are not independent or unrelated, and there is no serious burden on the examiner if the 8 inventions are searched together because the inventions do not require different field of search. This is not found persuasive because each invention has different design as evident by different distinct compositions of each invention, therefore, the prior art that anticipate one invention may not necessary anticipate the other. The search system and the focus of the invention are completely different, requiring an undue burden on the patent examiner. While searches may seem to be overlapping, however extensive since the patent examiner searches the databases mostly literally. Rarely do applicants present claims to an inventions where the distinctness of the invention are readily clear such as a chemical compound and a gene sequence. It is the responsibility of the examiner to enforce 35 USC 101, which allows the applicant to obtain a patent for a

single invention. In the opinion of the examiner the applicants present eight distinct inventions.

There is an examination and search burden for these patentably distinct inventions and require different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one invention would not likely be applicable to another invention; and/or the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given in the previous office action and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

The requirement is still deemed proper and is therefore made FINAL.

2. The species election between species of polar lipid, soluble fibers, nucleotide and additional components have been withdrawn.

3. Claims 39-60 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/13/2007.

Claims 1-38 are included in the prosecution.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-60 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over:

a) claims 1-29, 31-33, 35-72 of copending Application No. 10/435,367,

b) claims 1-62 of copending Application No.10/946,598,

c) claims 1-38 of copending Application No. 11/225,562, and

d) claims 1-59 of copending Application No. 11/500,835.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending applications and would be covered by any patent granted on the copending applications since the referenced copending applications and the instant application are claiming common subject matter as follows: the present claims and the conflicting copending claims are directed to nutritional composition, method of making the composition and method of its use, wherein the composition comprising soluble fibers, polar lipid, nutricine and protein. The present claims anticipate the claims of each of the copending applications.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The expression "other animals" render the claims indefinite because it is not clear to the examiner as what other animals other than equine have to have gastrointestinal tract that resembles the specified equine gastrointestinal tract to satisfy the limitations of the claims. *Ex parte Caldwell.* 1960 C.D. 58 (Comm'r Pat. 1906). Additionally, the specification does not set forth the metes and the bounds to the expression "other animals".

8. Claim 23 contains the trademark/trade name "Yeast Cell Extract (2006) by Lesaffre". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade

name is used to identify/describe yeast cell extract and it is not known what materials or ingredients other than yeast cell extract are in the trademark product, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 10-14, 33, 35 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by the product "Equilibra 500" with effective filing date 1989.

Present claim 1, in its broadest interpretation, is directed to composition comprising polar lipid, soluble fibers, nutricine and protein.

Equilibra 500 is nutricine based functional horse feed designed to create a 100% functioning gut to supply complementary advantages for the whole digestive system. Equilibra 500 comprises protein, galactolipids that are inherently polar lipid, antioxidant, vitamin E, minerals, and concentrated oat β glucan. Oat β glucan interfaces with the immune system cells to increase their effectiveness in response to non-self and inappropriate inflammation, therefore, oat β glucan reads on nutricine which strengthen immune system as claimed by claim 1. Vitamin E further reads on the medication claimed by claim 38.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1-17, 33-35, 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eqilibra 500 with effective date 1989 in view of US 6,410,067 ('067).

Eqilibra 500 is nutricine based functional horse feed designed to create a 100% functioning gut to supply complementary advantages for the whole digestive system. Equilibra 500 comprises protein, galactolipids (polar lipid), antioxidant, vitamin E, minerals, and concentrated oat β glucan. Oat β glucan interfaces with the immune system cells to increase their effectiveness in response to non-self and inappropriate

inflammation, therefore, oat β glucan reads on nutricine which strengthen immune system as claimed by claim 1. Vitamin E further reads on the medication claimed by claim 38.

Although Equilibra 500 teaches galactolipid, however, it does not explicitly teach galactolipid from oat oil and amount of oat oil as claimed by claims 2-9, the amount of soluble fibers as claimed by claims 15-17, and the amount of vitamin E as claimed by claim 34 and amount of mineral as claimed by claim 37.

US '067 teaches nutritional supplement for equine that meets the dietary needs of the neonates, athletics and geriatric horses, wherein the supplement comprises high proportion of fat up to 50% (abstract; col.2, lines 5-16; col.3, lines 10-12). The fat comprises oat oil (col.2, lines 5-25).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide nutricine based functional horse feed designed to create a 100% functioning gut to supply complementary advantages for the whole digestive system comprises protein, galactolipids, antioxidant, vitamin E, minerals, and concentrated oat β glucan as disclosed by Equilibra 500 and replace galactolipid with oat oil that inherently contains galactolipid and antioxidant, or further add oat oil as disclosed by US '067, motivated by the teaching of US '067 that supplements containing high proportion of oat oil meets the dietary needs of the neonates, athletics and geriatric horses, with reasonable expectation of having equine feed comprising oat oil that inherently contains galactolipids and antioxidant, protein, vitamin E, minerals, and concentrated oat β glucan that creates a 100% functioning gut to supply complementary

advantages for the whole digestive system and provides the needs for neonates, athletics and geriatric horses.

The available Equilibra 500 information, does not disclose the amount of the ingredients in the feed. However, those of ordinary skill in the art would have been readily optimized effective dosages as determined by good medical practice and the clinical condition of the individual horse to be fed. Determination of the appropriate dosage for treatment involving each of the above mentioned ingredients would have been routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation. One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

14. Claims 18-26, 36, 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over the teaching of Equilibra 500 by itself or combined with US '067, and further in view of the teaching of Alltech.

The teachings of Equilibra 500 and US '067 are previously discussed as set forth in sections 10 and 13 of this office action.

Although Equilibra teaches nutricine and protein in animal feed, however, it does not explicitly teach nucleotide from yeast as claimed by claims 18-26. Equilibra 500

teaches mineral, and recognized selenium, however, does not explicitly teach organic selenium as claimed by claims 36 and 37.

Alltech teaches enhancement of animal physiological condition through nutrition including Yea-Sacc®1026 as yeast culture as a performance enhancing for animals. Yea-Sate1026 is an active yeast culture comprised of viable cells from the strain Saccharomyces cerevisiae 1026. Yea-Sacc1026 is the only yeast culture that can be called rumen modifier. Alltech disclosed Bio-Mos that is a phosphorylated mannanoligosaccharide derived from the cell wall of the yeast and has been scientifically proven around the world to be beneficial to animals. Bio-Mos has shown positive results alone and in combination with antibiotic programs in animal diets. Alltech teaches that organic selenium is crucial mineral as protective in a number of metabolic diseases and essential for the basic functions of growth and reproduction and improves animal performance.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide nutricine based functional horse feed designed to create a 100% functioning gut to supply complementary advantages for the whole digestive system comprises protein, oat oil, vitamin E, minerals, and concentrated oat β glucan as disclosed by Equilibra 500 combined with US '067, and further add Bio-Mos which is yeast cell wall because Bio Mos is disclosed by Alltech as scientifically proven around the world to be beneficial to animals and has shown positive results alone and in combination with antibiotic programs in animal diets, with reasonable expectation of having horse feed comprises protein, oat oil, vitamin E, minerals, concentrated oat β

glucan and Bio-Mos that provides advantage to the animal digestive system and benefit the animal health in general. Additionally, one having ordinary skill in the art would have been motivated to replace the mineral disclosed by Equilibra 500 with organic selenium because organic selenium is crucial mineral as it is protective in a number of metabolic diseases and essential for the basic functions of growth and reproduction and improves animal performance, with reasonable expectation of having animal feed comprises protein, oat oil, vitamin E, organic selenium, concentrated oat β glucan and Bio-Mos that provides advantage to gastrointestinal tract and protect animal against metabolic diseases.

The available Alltech information, does not disclose the amount of Bio-Mos or organic selenium in the feed. However, those of ordinary skill in the art would have been readily optimized effective dosages as determined by good medical practice and the clinical condition of the individual horse to be fed. Determination of the appropriate dosage for treatment involving each of the above mentioned ingredients would have been routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation. One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

15. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over the teaching of Equilibra 500 by itself or combined with US '067, and further in view US 6,096,870 ('870).

The teachings of Equilibra by itself or combined with US '067 are previously discussed as set forth in sections 10 and 13 of this office action.

Although Equilibra teaches nutricine and protein in animal feed, however, it does not explicitly teach whey protein concentrate as claimed by claims 27-28.

US '870 teaches whey protein concentrate including immunoglobulin and lacta-albumin used in animal feed (col.5, lines 7-25; col.11, lines 6-15). The reference disclosed whey protein represent a significant source of nutrition for a majority of the world's human and non-human animal (col.1, lines 15-18).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide nutricine based functional horse feed designed to create a 100% functioning gut to supply complementary advantages for the whole digestive system comprises protein, oat oil, vitamin E, minerals, and concentrated oat β glucan as disclosed by Equilibra 500 combined with US '067, and replace protein with whey protein concentrate disclosed by US '870, motivated by the teaching of US '870 that whey protein represent a significant source of nutrition for a majority of the world's human and non-human animal, with reasonable expectation of having animal feed comprising oat oil, whey protein concentrate, vitamin E, minerals, and concentrated oat β glucan that provides advantages for the whole digestive system and further provides significant source of nutrition.

16. Claims 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over the teaching of Equilibra by itself or combined with US '067, and further in view of the article "Arteriovenous difference for glutamine in equine gastrointestinal tract" by Duckworth et al.

The teachings of Equilibra by itself or combined with US '067 are previously discussed as set forth in sections 10 and 13 of this office action.

Although Equilibra teaches nutricine and protein in animal feed, however, it does not explicitly teach glutamine as claimed by claims 29-32.

Duckworth et al. teach glutamine can be effectively metabolized in horses and glutamine nutrition may be beneficial in healthy horses or horses with varieties of intestinal disorders (page 1867, right column).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide nutricine based functional horse feed designed to create a 100% functioning gut to supply complementary advantages for the whole digestive system comprises protein, oat oil, vitamin E, minerals, and concentrated oat β glucan as disclosed by Equilibra 500 combined with US '067, and further add glutamine taught by Duckworth et al. to the feed because Duckworth et al. teach that glutamine is effectively metabolized in horses and glutamine nutrition may be beneficial in healthy horses or horses with varieties of intestinal disorders, with reasonable expectation of having animal feed comprises protein, oat oil, vitamin E, mineral, concentrated oat β glucan and glutamine that provides advantage to gastrointestinal tract and successfully

protects the mucosa from gastric ulcer formation and provides benefits to healthy horses or horses with gastrointestinal disorders.

Duckworth et al does not disclose the amount of glutamine in the feed. However, those of ordinary skill in the art would have been readily optimized effective dosages as determined by good medical practice and the clinical condition of the individual horse to be fed. Determination of the appropriate dosage for treatment involving each of the above mentioned ingredients would have been routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation. One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Isis A Ghali
Primary Examiner
Art Unit 1611

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ISIS GHALI
PRIMARY EXAMINER